

**TESTIMONY OF**  
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**BEFORE THE**  
**COMMITTEE ON ENERGY AND COMMERCE**  
**SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS**  
**U.S. HOUSE OF REPRESENTATIVES**

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Good morning, Chairman Stupak and Members of the Committee. My name is George Gray, and I am the Assistant Administrator for Research and Development at the U.S. Environmental Protection Agency (EPA, or Agency). I also serve as EPA's Science Advisor. Thank you for this opportunity to appear before the Subcommittee to discuss three important topics: First, our ongoing efforts to maintain the highest levels of scientific integrity in research, assessments, and analyses; second, EPA's recent improvements to the Integrated Risk Information System (IRIS); and third, the Agency's independent, external peer-review process.

**Scientific Integrity**

EPA conducts research that provides scientific and technical information to support our mission to protect public health and the environment. Our scientists conduct research independent of political influence, publish results in peer-reviewed journals, present findings at scientific and technical conferences, and speak openly with the public about their work.

We are committed to using the best-available science and the most defensible science-policy choices to achieve our strategic goals and fulfill our mission. Science informs, and provides a foundation for, EPA's regulatory decisions. At the same time, it is important to recognize that what often appear to be purely scientific questions or assessments generally involve both

"science" and "science-policy" considerations. For example, developing risk values requires many decisions, choices, and assumptions that are generally guided by Agency science policy.

While it is important to integrate our scientists' research and development products with the Agency's regulatory needs, it is also vital that the research itself is independent, objective, transparent, and of the highest quality. During the past several years, EPA has taken a number of steps to maintain a program of sound scientific research to inform Agency decisions without allowing regulatory objectives to guide or distort scientific findings or analyses. These steps have included open, transparent, and peer-reviewed research planning; competitively awarded extramural research grants; independent and external peer review of our science publications, assessments, and documents; and rigorous evaluations of EPA's research laboratories and centers.

EPA's science program is at the leading edge in many areas of science and technology. With our focus on high-quality, relevant support for the Agency's activities and decisions, we are well-positioned to address the challenges of the 21<sup>st</sup> century. We constantly look for ways to build on our strengths so that EPA's decisions and actions continue to be informed by the best-available science and the most defensible science-policy choices.

### **EPA's Scientific Staff**

According to Thomson Scientific's *Essential Science Indicators*, over 20 percent of our publications are "highly cited" and over 30 percent are published in "high-impact" journals.

Our scientists are also active participants in many scientific organizations, including the American Public Health Association, Association for Practical and Professional Ethics, Geological Society of America, American Geophysical Union, Ecological Society of America, Air and Waste Management Association, Society for Risk Analysis, International Society of Exposure Analysis, Society of Toxicology, and more. Many of our scientists hold leadership positions in, and have received prestigious awards from, major scientific organizations such as the Intergovernmental Forum on Chemical Safety, International Commission on Radiological Protection, and Society of Toxicology, as well as major research universities.

Considering the scientific and technical talent in our organization, and our experts' clear commitment to public service, it is my aspiration to have EPA be the premier environmental-science organization in the federal government. We have demonstrated positive momentum toward this goal with many achievements, such as:

- Award-winning tools and strategies to protect public health developed by our National Homeland Security Research Center;
- Cutting-edge models to test chemical effects and interactions developed by our National Center for Computational Toxicology;
- Ground-breaking reports on the effects of climate change to inform national and international dialogues developed by our Global Change Research Program; and
- Grants awarded to scientists across the nation to research environmental challenges and develop innovative solutions through our National Center for Environmental Research.

### **Science Planning and Science Management at EPA**

EPA's first priority is "doing the right science." A number of sources, both internal and external to the Agency, provide information and guidance on how EPA can prioritize its research. EPA's Strategic Plan serves as the first organizing principle for EPA's research agenda. Next, EPA's Program and Regional Offices communicate their science needs based on their unique policy and regulatory responsibilities. EPA's Office of the Science Advisor also provides critical input. The Agency must incorporate into its research planning Congressional mandates, the priorities of the Administration and other agencies, as well as advice from external advisory committees. Other research stakeholders, including non-governmental organizations and industry, may voice their priorities. EPA management and directors of research take input from these various sources into account when setting the research agenda.

"Doing the science right" by promoting effective management and implementation of our research strategies is an equally important responsibility and serves to strengthen scientific integrity. It is vital that EPA strive for the highest quality and credibility in its activities and decision-making processes if the American public is to have confidence in our decisions. To this end, EPA scientists, managers, and union representatives jointly developed the EPA *Principles of Scientific Integrity* under the auspices of the National Partnership Council. To ensure that management and staff understood the importance of scientific integrity at all levels

of the organization, the release of this document was followed with online training. The

Principles include the following:

- Honesty - EPA employees are responsible and accountable in all aspects of their science.
- Accuracy - Employees represent their work, and the work of others, fairly and accurately.
- Recognition - The intellectual contributions of others are recognized and acknowledged.
- Freedom from conflicts - All science is conducted in an atmosphere free of conflicts of interest.
- Knowledge of statutory authorities - Know and understand the statutes and regulations that guide EPA's work.
- Responsibility - Breaches of these principles must be promptly reported when discovered.
- Open-mindedness - Differing views and opinions on scientific and technical matters are a welcome part of the scientific process.

EPA's Criteria for Transparency further support the Agency's scientific quality. The Criteria for Transparency were written to ensure that the public would understand all the steps, logic, key assumptions, limitations, and decisions in the assessment process, and also comprehend the supporting rationale that led to a particular decision or outcome. EPA's 2000 *Risk*

*Characterization Handbook* states that transparency includes full disclosure of the following:

- The assessment approach employed;
- The use of assumptions and their impact on the assessment;
- The use of extrapolations and their impact on the assessment;
- The use of models vs. measurements and their impact on the assessment;
- Plausible alternatives and the choices made among those alternatives;
- The impacts of one choice vs. another on the assessment;
- Significant data gaps and their implications for the assessment;
- The scientific conclusions identified separately from default assumptions and policy calls;
- The major risk conclusions and the assessor's confidence and uncertainties in them; and
- The relative strength of each risk assessment component and its impact on the overall assessment.

To monitor performance, EPA'S Office of Research and Development (ORD) requests feedback from EPA Program and Regional Offices on the timeliness and quality of its research. ORD research programs also undergo formal performance evaluations by the Office of Management and Budget by way of OMB's Performance Assessment Rating Tool (PART). Additionally, the Board of Scientific Counselors, Science Advisory Board, National Academies of Science, and other advisory panels provide program evaluations that facilitate continuous improvement and ensure ORD is advancing the state of the science in key areas. Members of EPA's advisory boards are non-EPA scientists, engineers, and social scientists who are recognized experts in their fields. They come from academia, industry, government, research institutes, and non-governmental organizations throughout the United States. EPA chooses them for their demonstrated ability to examine and analyze environmental issues with objectivity and for their interpersonal, oral and written communication, and consensus-building skills.

In sum, ORD's research is guided by strategic directions and stakeholder input, adjusted according to annual budget decisions, evaluated to ensure effective and efficient management, and ultimately applied to inform environmental decision-making.

### **The Science to Decision-Making Continuum at EPA**

Similar to other federal agencies that are required to produce both scientific assessments and regulatory decisions, EPA views the relationships between science, science-policy, and official Agency decision-making as a continuum.

To start, EPA science is conducted by individuals and teams working in our laboratories or in the field. All of their work is reviewed by subject-matter experts in accordance with EPA's highly regarded peer-review process and information-quality guidelines. Once an EPA scientific product meets scientific standards of quality and credibility, scientists are encouraged to publish and otherwise communicate their findings. Note that these independent, scientific findings do not necessarily represent official Agency policy positions, as national policies must also take other factors into account.

Science policy is an integral part of the continuum. Because the scientific method encourages critical thinking and professional disagreement, it does not commonly lend itself to a "bright line" that decision-makers can use as a reliable reference point. A range of reasonable and

scientifically defensible options or decisions are usually available, and there is rarely a single “best answer” for use in decision-making. Scientific assessments also entail varying degrees of uncertainty and many decisions, choices, and assumptions must be made based on science-policy considerations.

To meet our statutory requirements, we often cannot wait for independent scientific findings to converge on a solution—this would cause long delays in environmental decision-making. Therefore, we rely on science-policy considerations, which often entail synthesizing and assessing a range of scientific opinions and data points. This process also involves filling in knowledge gaps in the body of technical information, and where necessary, using weight-of-evidence approaches to make scientific inferences or assumptions. The scientific models that inform most national policies require this kind of give and take. This work draws on expert insights from multiple scientific disciplines, and it is further strengthened by Agency, interagency, and public review.

Decision-making is further along the continuum. Science, however, is but one aspect of EPA's regulatory decisions. Other important considerations need to be factored into EPA's decisions without compromising scientific integrity, the Agency's mission, or statutory mandates. These considerations include technological feasibility, implementation costs, local autonomy versus federal control, justice, and equity. The impacts or limitations of these non-science factors, as well as the current state of the science, will influence how scientific considerations are brought to bear on environmental decisions facing the Agency.

Administrator Johnson and his leadership team give serious weight to science and science-policy choices in developing options for national policy. Nevertheless, the science to decision-making continuum does not end with regulation and rules. Every Agency decision feeds back into science and science-policy considerations as we monitor the effectiveness of our national policies and use updated information about changes in the quality of human health and the environment to adjust our policies over time.

### **EPA's Integrated Risk Information System (IRIS)**

The IRIS program, which began in the mid-1980s, includes a repository of human health risk information on the potential adverse effects of long-term, or chronic, exposure to over 540

potential environmental contaminants. At the time the program was established, it was clear that the toxicity values that were being developed by EPA were not internally consistent across the Agency. For example, EPA's Program Offices were publishing toxicity values for a particular chemical in rulemakings and other policy documents that were orders of magnitude different. EPA developed these toxicity values using the same set of scientific data, but they were based on different human health endpoints or default uncertainty factors. Thus, EPA formed IRIS in response to a critical need to have Agency-wide toxicity values in one place. IRIS files included narratives detailing supporting studies, key assumptions, and choices. EPA health scientists developed and reviewed all of this information.

IRIS was originally intended to be an internal system that provided EPA risk assessors and managers with an EPA consensus position on the potential human health hazard and dose-response information for environmental contaminants of interest to Agency Programs and Regions. Word spread quickly about the existence of IRIS and many asked to make it a publicly available system. State and local public health and environmental agencies, as well as the regulated community, requested access to the IRIS information. Therefore, in the late 1980's, EPA made IRIS available to the public. EPA was pleased to share this information resource with a large, external user community. IRIS first became available on a dial-up service and later through the National Library of Medicine's TOXNET family of information resources, and then on the Internet. The IRIS Web site is currently accessed over 20,000 times per day with inquiries coming from over 100 countries.

Today's IRIS program presents a wealth of important information to decision makers and environmental managers. The risk information in IRIS can include quantitative risk estimates for both cancer and non-cancer effects. In addition, extensive narratives, or qualitative risk information, present a full discussion of the peer-reviewed scientific literature used in the assessment, the EPA confidence in the IRIS non-cancer risk estimates, and an explanation of the judgments (including application of default approaches and uncertainty factors) that the Agency must make in the face of inadequate data.

### **Risk Assessment and Risk Management**

A significant part of EPA's mission to protect public health and the environment is to regulate, when necessary, the release of contaminants into the nation's air, water, and soil. As first

outlined by the National Academy of Sciences (NAS) in its seminal 1983 report, “Risk Assessment in the Federal Government: Managing the Process,” commonly called the “Red Book,”<sup>1</sup> there are two distinct steps that should be used in the federal government to assess and manage risks. These steps are *risk assessment* and *risk management*.

Risk assessment, as defined by the NAS, is “the characterization of the potential adverse health effects of human exposures to environmental hazards” (p. 18). Risk assessments can entail either quantitative or qualitative expressions of risk, and should include characterization of the uncertainties inherent in the process of inferring risk. The risk assessment process has four components: hazard identification, dose-response evaluation, exposure assessment, and risk characterization.

Risk management is defined by the NAS as “the process of evaluating alternative regulatory options and selecting among them” (p. 18). A risk assessment may serve as one of the bases of risk management.

An IRIS assessment is a risk assessment, albeit not a complete one. IRIS includes information on hazard identification and dose-response evaluation but does not include information on exposure and risk characterization. Government and private entities use IRIS—combined with exposure information, public health concerns, social considerations, as well as statutory and economic factors—to characterize the public-health risks of chemical substances and support risk-management decisions.

It is important to recognize that the risk-assessment process consists of both “science” and “science policy” components. This is an important distinction that is often overlooked, yet the 1983 NAS “Red Book” addressed this issue in its first chapter.<sup>2</sup> For example, conducting a toxicity study on animals in a lab is a science activity. In contrast, IRIS assessments must synthesize and assess a broad range of scientific findings and opinions.

The situation I referenced earlier, in which EPA Program Offices published different toxicity values for a particular chemical in spite of their access to the same set of scientific data, illustrates the distinction between science and science policy. In IRIS assessments, judgments

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<sup>1</sup> National Academies Press, ISBN: 0309033497

<sup>2</sup> See page 28 and the section entitled “Scientific and Policy Judgments in Risk Assessment”



and choices must be made about the most appropriate assumptions, data sets, health endpoints, and models to use in deriving toxicity values. These science-policy choices are important because the science alone is not sufficiently precise to provide definitive answers. For this reason, guidance documents such as EPA's "Guidelines for Carcinogen Risk Assessment" were developed and approved through the Agency's Science Policy Council to inform the many choices in the risk-assessment process.

### **Revisions to the IRIS Process**

The IRIS process has evolved over time in areas including the following: setting the annual IRIS agenda, level of independent/external peer review, and opportunities for public and interagency review. Because IRIS began as an internal EPA resource, the agenda for developing IRIS assessments focused on those chemical assessments of interest to EPA's Program Offices and Regions. Now EPA develops an annual agenda for the IRIS program and announces new assessments under review in the Federal Register. EPA uses five general criteria to determine which new chemicals to assess: (1) potential public health impact; (2) EPA statutory, regulatory, or Program/Region-specific implementation needs; (3) availability of new scientific information or methodology that might significantly change current IRIS information; (4) interest to other governmental agencies or the public; and (5) availability of other scientific assessment documents that could serve as a basis for an IRIS assessment.

In recent years, the IRIS Program has also sought nominations for IRIS chemical reviews from the public and other federal agencies. The list of new or updated assessments chosen for potential development is published in the Federal Register as part of the IRIS annual agenda. The Agency is also working to improve the prioritization process to more appropriately capture relative priorities of individual chemical assessments under development. EPA conducts an initial literature search for each of the assessments added to the IRIS agenda, and the results are posted on the IRIS web site ([www.epa.gov/iris](http://www.epa.gov/iris)). At this point, EPA invites the public and other agencies to review the literature-search results and submit additional information to EPA.

Other recent changes to the IRIS process include creation of a chemical-assessment tracking system (IRISTrack) on the IRIS Web site to inform the public and stakeholders of the following: (1) the status of the IRIS assessments that are underway, (2) new opportunities for the public and other agencies to review and comment on the qualitative and draft IRIS assessments

(including the ability to participate in “listening sessions” held during the public comment period), and (3) the availability of enhanced independent/external peer reviews of draft IRIS assessments.

The IRIS program has benefited from an expansion of scientific staff and a significantly increased budget over the last few years. Since FY 2003, EPA has nearly tripled the number of IRIS staff to 37.0 full-time equivalents. Through its FY 2009 request, EPA has also sought to quadruple the IRIS budget to \$9.4 million.

In 2005, EPA initiated a formal process to document the steps in the IRIS process, including formalizing recent improvements to the process. On April 10, 2008, EPA announced the revised IRIS process—the first time in IRIS history that EPA has transparently documented the process and made it available to the public. Prior to the release, the IRIS process had often been viewed as a “black box” both within and outside of the Agency; it was unclear what steps comprised the process, what the timing was for each step, or where opportunities existed for internal and external involvement. Improvements to the IRIS process help define critical and appropriate roles for public and interagency comments and interactions, and promote greater communication and sharing of information between all interested parties and EPA. The revised IRIS process is designed to provide greater transparency, objectivity, balance, rigor, and predictability in IRIS assessments.

Delays in the completion of IRIS assessments have been a long-standing problem at EPA for a number of reasons, including the growing complexity of assessments, the lack of clear timeframes, etc. Prior IRIS assessments took an average of five years to complete, and EPA has been working on some assessments for a decade or longer. The revised process was designed to help address these delays, in part, by allowing for input from various stakeholders (e.g., EPA Program and Regional Offices, other agencies, scientific organizations, NGOs, the public) early in the process and providing clear descriptions and timeframes for each step. This approach helps EPA to collect necessary information while holding itself accountable to assessment timelines.

The early involvement of various stakeholders is consistent with recommendations from EPA’s Science Advisory Board (SAB) as well as a prior report by the Government Accountability Office (GAO). In a September 26, 2000 letter to Administrator Carol Browner, SAB noted that “critical

data” were often missing from IRIS risk assessments. SAB suggested that one way to enhance the quality of toxicologic evaluations was to “make the IRIS process open to public stakeholder review in a more formal manner.” A 2006 report by GAO noted the following: “...several experts said that increased involvement with a broad range of stakeholders early in the planning process would help identify alternative methods and models and obtain stakeholder concurrence with the agency’s approach.”<sup>3</sup> The new process therefore allows the EPA access to a wide range of scientific data, expertise, and knowledge that can be used to produce timely and high-quality IRIS assessments. However, it should be noted that all draft IRIS assessments are peer reviewed by outside experts, and all final decisions on IRIS content remain with EPA.

It is also important to recognize that many of the assessments today are more complex than ever before. For example, some chemicals have extensive toxicity testing data that must be reviewed and analyzed; new data are now available for assessing the mode of action of many chemicals; and more sophisticated statistical and modeling techniques are now available. Considering the growing complexity of IRIS assessments, recent peer reviews of IRIS assessments by the NAS and EPA’s SAB have recommended that EPA do a better job of incorporating quantitative uncertainty analyses. The timelines in the revised IRIS process allow EPA to address the additional information and analysis in today’s complex assessments.

An important aspect of the revised process includes “mission-critical” chemicals that will be determined by a sponsoring agency together with EPA. A mission-critical chemical is one that is an integral component to the successful and safe conduct of an agency’s mission in any or all phases of its operations. Agencies must identify to EPA’s Office of Research and Development (ORD) those chemicals on the IRIS Program Annual Agenda that they determine meet this definition. They must generate a report documenting what types of new research will address significant data gaps and whether such research can be conducted within the allotted time frame. It is ultimately up to EPA to allow new research to be conducted. We do not anticipate that many chemicals will receive the mission-critical designation each year or that additional studies will be requested for all mission-critical chemicals. However, new studies could help fill important data gaps to ensure assessments of the highest quality.

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<sup>3</sup> GAO-06-595: “Human Health Risk Assessment: EPA Has Taken Steps to Strengthen Its Process but Improvements Needed in Planning, Data Development, and Training”

Independent, external peer reviews, which are described in more detail below, are another hallmark of EPA's commitment to ensuring high-quality science. Consistent with past practices, the revised IRIS process specifies that all draft IRIS Toxicological Reviews will undergo peer review by a panel of outside, independent experts. A small number of complex or high-profile chemicals may undergo more in-depth SAB or NAS peer reviews. As part of the revised IRIS process, external peer reviewers will also, for the first time, have an opportunity to review the revised IRIS Toxicological Review and comment on ORD's responses to the peer reviewers and public comments. This is an important step that is consistent with other peer review practices, such as publishing in the peer-reviewed literature, to reveal when peer reviewer comments are adequately addressed or sufficient rationale is provided for not addressing such comments.

The revised IRIS process meets many of the recommendations of the 2008 GAO report entitled "Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals."<sup>4</sup> Specifically, the revised process (1) clearly defines and documents a streamlined IRIS assessment process; (2) sets time limits for all parties, including OMB and other federal agencies, to provide comments to EPA on draft IRIS assessments; (3) defines the appropriate role of external federal agencies in EPA's IRIS assessment process; and (4) determines the types of IRIS assessments to conduct on the basis of the needs of EPA's Program Offices and other users.

Although EPA's revised IRIS process addresses many of the recommendations, in the 2008 GAO report, it is our position that the report incorrectly characterizes of several key issues. The report suggests that only pure science is involved in the risk-assessment process. In reality, all risk assessments (including IRIS assessments) have always included a mix of science and science policy, as acknowledged in the 1983 NAS "Red Book."

The GAO report also mischaracterizes the interagency review process at EPA. Specifically, to ensure that scientists and policymakers are able to have full and frank discussions without being concerned about how these discussions may be viewed or misrepresented, all internal EPA comments and interagency comments, including disposition documents, on draft IRIS assessments are considered "deliberative" and do not become a part of the public record. This is not a new or unique process. This is the same protection allowed in many other policy-making settings at EPA, and other federal agencies follow similar processes. Moreover, once

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<sup>4</sup> [GAO-08-743T](#)

EPA comes to a conclusion and releases its external review draft, the assessment undergoes a transparent process of public comment and external peer review. The GAO report incorrectly suggests that EPA will not have the final say on the content of IRIS assessments under the revised process given the participation by other agencies. However, EPA's revised IRIS process makes it clear that all final decisions remain with EPA.

The revised IRIS process is designed to enhance the quality and timeliness of future assessments. EPA now needs time to implement and evaluate the new process.

### **Independent, External Peer Review**

As indicated above, a practical and effective way that EPA maintains the integrity of its scientific programs and products is through independent, external peer review—the evaluation of Agency programs and products by panels of outside experts. EPA has a very strong peer-review program to ensure that only high-quality science is released and/or used by the Agency. Hundreds of Agency products undergo peer review each year, and nearly 90 percent are reviewed by independent experts who are not affiliated with the Agency.

EPA's Science Policy Council maintains our Peer Review Handbook, a “how-to” manual that is used by staff across the Agency. In addition, external stakeholders often refer to the Handbook as a model of strong peer-review practices, which include: peer review by experts who are independent of the Agency; public review and comment as appropriate; and maintenance of transparent, public records of scientific products at relevant stages of development. Our updated Peer Review Policy (2006) and 3rd edition of the Peer Review Handbook (2006) benefit from insights gained by implementing the program over the last decade. The 2006 Handbook clarifies ethical standards in order to improve understanding and compliance on the part of staff and management.

Our peer-review program fits within the context of a larger, Agency-wide quality system. EPA's quality system is the means by which we manage our scientific information in a systematic, organized manner and it provides a framework for planning, implementing, and assessing EPA's scientific work. Our peer-review policies also incorporate the provisions of the Office of Management and Budget's (OMB) Final Information Quality Bulletin for Peer Review. This Bulletin contains provisions for conducting peer review at all federal agencies in order to

enhance transparency and accountability and applies to “influential scientific information” and “highly influential scientific assessments.” OMB’s Information Quality (IQ) Guidelines, together with our own IQ guidelines, are important elements in our quality system, as required by Congress in what has become known as the Information Quality Act.

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The cornerstone of the external peer-review process is the peer reviewer, the individual scientist or other expert who graciously agrees to take on the responsibility of closely and impartially examining EPA research programs and results. Identifying and selecting potential peer reviewers are critical components of a credible peer-review process. A clearly demonstrated high level of expertise in the appropriate field is a minimum qualification. In addition, potential or perceived conflicts of interest must be disclosed to allow agencies to make informed judgments about the appropriateness of each reviewer. For example, direct financial gain is an obvious source of conflict of interest. Other examples include a professional stake in an issue, illustrated by serving as an expert witness or advocating for a particular view on the topic subject to peer review.

While disclosure of a potential or perceived conflict of interest is not necessarily grounds for keeping a potential reviewer from participating, failure to disclose certainly is. This issue becomes especially troublesome when the failure to disclose becomes known once the peer-review process has begun or been completed.

EPA, like other federal agencies and credible scientific bodies, has gone to great lengths to ensure that all potential or perceived conflicts of interest of peer reviewers are disclosed during the selection and review process. For example, questionnaires have been developed that seek to identify all potential issues, and peer reviewers are asked to certify their answers during the initial process and again before the review begins. It is important that reviewers take these questions seriously and respond completely so that an unnecessary and potentially embarrassing disqualification does not take place.

The peer review of assessments, which often synthesize multiple scientific studies, may include a number of steps: internal peer consultation, intra-Agency (internal EPA) review, interagency review, and independent/external peer review. For example, to enhance the quality and transparency of EPA’s IRIS assessments, the revised IRIS process specifies that each Toxicological Profile undergo peer review as follows:

- Internal Peer Consultation: Internal (EPA) peer reviewers are selected to provide detailed scientific feedback on the draft assessment.
- Intra-Agency Review: The draft assessment is reviewed by a standing group of senior health scientists representing EPA's Offices and Regions and by selected senior health scientists with scientific expertise relevant to the substance under review.
- Interagency Review: The revised draft assessment is distributed through the Office of Management and Budget for review by scientists in other federal agencies.
- External Peer Review: EPA obtains external peer review, typically via a panel meeting that is open to the public. At this time, the draft assessment is posted on the internet for public comment. EPA may submit more challenging assessments to high-level advisory panels, such as the EPA Science Advisory Board or National Academies of Science.

Peer review is also conducted at a higher level of planning and management, as discussed previously in the section on Science Planning and Management. For example, EPA's Science Advisory Board, among other bodies, reviews the Agency's research strategy and programs. SAB reviews provide critical cross-Agency perspectives as EPA establishes its research priorities in the near and long-term. Additionally, EPA ensures systematic, external peer review of research programs in its Office of Research and Development (ORD) by the Board of Scientific Counselors and others. Each ORD research program undergoes a detailed review approximately every four years, with a mid-cycle review after two years. These external perspectives promote continuous improvement and help EPA to focus on the highest-priority research needs to protect human health and the environment.

### **Conclusion**

Thank you, Chairman Stupak and members of the Subcommittee for this opportunity to discuss scientific integrity at the EPA, the IRIS program, and our rigorous peer-review process. I look forward to answering any questions you may have.